

AUG 02 2002

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Attachment 17

**510(k) SUMMARY****POWDER FREE GREEN COLOUR NITRILE RUBBER EXAMINATION GLOVES**

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| Submitter's Name  | LATEXX MANUFACTURING SDN. BHD.   |
| Submitter's Address   | PT 5054, Kamunting Industrial Estate<br>P.O. Box 9, 34600 Taiping, Perak<br>Malaysia   |
| Submitter's Phone Number                                      | 605 891 1111   |
| Submitter's Fax Number  | 605 891 1088   |
| Name of Contact Person  | Teoh, Choh Shee  |
| Date of Preparation   | June 15, 2002  |
| Name of Device  | <p>Trade Name : Medtexx™ Powder Free Green Colour Nitrile Rubber Examination Glove</p> <p>Common Name : Nitrile Rubber Examination Gloves</p> <p>FDA SE Classification Name : Patient Examination Gloves, Powder-free</p> <p>FDA Classification Product Code : Nitrile – 80LZA</p>   |
| Legally Marketed Device to Which Equivalency is Being Claimed | Medtexx™ Powder Free Green Colour Nitrile Rubber Examination Glove as described in this 510k Notification is substantially equivalent to the current Class I patient examination glove bearing the product code 80LZA (21CFR 880.6250). It meets all the current specifications listed under the ASTM Specification D 6319–00a, Standard Specification for Nitrile Examination Gloves for Medical Application. |
| Description of the Device                                     | Medtexx™ Powder Free Green Colour Nitrile Rubber Examination Glove meets all the current specifications listed under the ASTM Specification D 6319–00, Standard Specification for Nitrile Examination Gloves for Medical Application. They are made from nitrile rubber latex compound. They are natural white in color and are powder free.   |

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| Intended Use of the Device  | Medtexx™ Powder Free Green Colour Nitrile Rubber Examination Glove is intended for single use for medical purposes that is worn on the hand of health care and similar personnel to prevent contamination between the health care personnel and the patients.  |
| Summary of Technological Characteristics Compared to the Predicate Device | There is no different technological characteristic. Gloves are made from nitrile rubber latex compound and the initial products are low powdered nitrile gloves. These gloves are then further processed into powder free gloves using the existing technology, i.e. chlorination and multiple washing and rinsing processes.  |
| Brief Description of Non-clinical Tests                                   | <p>Testing performed per ASTM D 6319 – 00a, Standard Specification for Nitrile Examination Gloves for Medical Application and 21 CFR 800.20. Gloves meet all the current ASTM D 6319–00a.</p> <p>Primary skin irritation testing in the rabbit and delayed contact sensitization testing in the guinea pig indicate no irritation or sensitization.</p> <p>Final product is negative for the presence of starch using the USP iodine test.</p> |
| Brief Description of Clinical Tests                                       | No new clinical tests were conducted under this 510(k).  |
| Conclusions Drawn from the Non-clinical and Clinical Tests                | Non-clinical laboratory and animal based test data indicate that the powder-free product meets all performance and biocompatibility requirements.  |
| Other Information Deemed Necessary by FDA                                 | Not applicable.  |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 02 2002

Latexx Manufacturing Sdn. Bhd.  
C/O Mr. Law Siau Woei  
Medtexx Partners Incorporated  
216 Charles Street  
Hackensack, New Jersey 07601

Re: K022101

Trade/Device Name: Powder Free Nitrile Rubber Examination Glove,  
Green Color

Regulation Number: 880.6250

Regulation Name: Patient Examination Gloves

Regulatory Class: I

Product Code: LZA

Dated: June 15, 2002

Received: June 28, 2002

Dear Mr. Woei:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

  
f. Timothy A. Ulatowski

Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Medtexx™ Green Colour Powder-free  
Nitrile Rubber Examination Gloves



## INDICATIONS FOR USE

Applicant : LATEXX MANUFACTURING SDN.BHD.  
 PT 5054, Kamunting Industrial Estate  
 P.O. Box 9  
 34600 Taiping Perak  
 MALAYSIA

510(k) Number : K022101 \*

Device Name : POWDER FREE NITRILE RUBBER  
EXAMINATION GLOVE, GREEN COLOUR.

Indications For Use :

*Powder Free Nitrile Rubber Examination Glove, Green Colour, is a single use device intended for medical purposes that is worn on the hand of healthcare and similar personnel to prevent contamination between the healthcare personnel and the patient.*

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Concurrence of CDRH Office of Device Evaluation (ODE)

*Olin S. Lin*  
 (Division Sign-Off)  
 Division of Dental, Infection Control,  
 and General Hospital Devices  
 File Number K022101

Prescription Use \_\_\_\_\_  
 Per 21 CFR 801.109

OR

Over-The-Counter \_\_\_\_\_